Exhibit 10

510(k) Summary

FEB – 6 2009

Submitter Name: Submitter Address:	ClearCorrect, Inc. 5200 Mitchelldale St., Ste F-26 Houston, TX 77092
Phone Number: Fax Number:	713-850-1036 713-248-9415
Contact Person:	Jarrett Pumphrey
Date Prepared:	30 August 2008
Device Trade Name:	ClearCorrect
Common Name	Clear Braces
Classification Name, Number & Product Code:	Sequential Aligner 852.5470 NXC
Predicate Devices:	Invisalign/Align System, Align Technology Inc., K981095 Clear Image Aligners, Specialty Appliances Works, Inc., K071970
Device Description and Statement of Intended Use	Device Description: The ClearCorrect device is fabricated of clear, thin, thermoformed polycarbonate plastic in a sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner. Intended Use: The CearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.
Summary of Technological Characteristics	A dental health care professional (e.g. orthodontist or dentist), prescribes the ClearCorrect system based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth,

and completes a prescription form The molds and prescription are sent to ClearCorrect. Utilizing standard, dental software used for tooth alignment, ClearCorrect designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, ClearCorrect produces the trays, which are formed of clear, thin, thermoformed polycarbonate plastic. The trays are sent back to the dentist, who then provides them to the patient, confirming fit and design. Over a period of months, additional trays are provided sequentially to the patient by the physician to gradually move the target teeth to the desired position. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced above.

Conclusion

The information discussed above demonstrates that the ClearCorrect device is substantially equivalent to the predicate devices

Declarations

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	ClearCorrect	Invisalign/Align System	Clear Image Aligners
510(k) Number	Not yet assigned	K981095	K071970
Manufacturer	ClearCorrect, Inc.	Align Technology Inc	Specialty Appliances Works, Inc
Classification # & Product Code	852.5470 NXC	852.5470 NXC	852.5470 NXC
Intended Use	The CearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.	The Align System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Align System positions teeth by way of continuous gentle force.	The Clear ImageTM Aligners system is intended to correct minor discrepancies in the alignment of malocclueded anterior teeth on patients with permanent dentition (second molars) by moving the teeth with a progressive series of clear thin, thermoformed plastic aligners, fabricated in stages to gradually align the teeth over a period of several months. The aligners are completely removable by the patient and may be discontinued at any time.
Mode of Action	Alignment of teeth by sequential use of preformed plastic trays.	Alignment of teeth by sequential use of preformed plastic trays.	Alignment of teeth by sequential use of preformed plastic trays.
Material	Thermoformed polycarbonate	Thermoformed polycarbonate	Thermoformed polycarbonate
OTC or Rx	Rx	Rx	Rx

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ClearCorrect, Incorporated
c/o Mr. William Greenrose
President
Qserve America, Incorporated
220 River Road
Claremont, New Hampshire 03743

FEB - 6 2009

Re: K082556
Trade/Device Name: ClearCorrect
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: January 15, 2009
Received: January 16, 2009

Dear Mr. Greenrose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.1 Indications for Use Statement

510(k) Number (if known): K082556

Device Name: ClearCorrect

Indications for Use:

The CearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082556